

**1.0 510(k) Summary****1.1 Date of Summary Preparation:** March 30, 2007

**1.2 Manufacturers Contact Person:** Howard Mann APR - 2 2007  
 Regulatory Affairs  
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 PuriCore Inc  
 508 Lapp Road  
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**1.3 Trade Name:** Sterilox ~~Liquid Chemical~~ High Level Disinfectant System**1.4**

Classification Name	Product Code	Class	Classification Reference
Classification Name	Product Code	Class	21CFR §
High Level Disinfectant	MED	II	880.6885

**1.5 Special Controls:**

Content and Format of Pre-Market Notification [510(k)] Submissions for Liquid Chemical Sterilants/High Level Disinfectants, dated January 3, 2000.

**1.6 Indications for Use:**

Sterilox™ is a high level disinfectant system intended for processing heat sensitive medical devices when used according to the User Manual with an immersion time of ten (10) minutes at 30°C. Sterilox is a single use product generated on site by the Maxigen II (E200) generator for use at its MRC of 400-450 ppm (AFC). The Sterilox high level disinfectant is intended for processing only in an automated endoscope reprocessor or washer disinfectant with FDA-cleared capability to maintain the solution temperature at 30°C.

The device is intended for use by qualified health care personnel trained in its use.

**1.7 Device Description:**

The Sterilox Liquid Chemical High Level Disinfectant System is an apparatus that produces a single use High Level Disinfectant by on-site electrochemical activation (electrolysis) of a dilute aqueous solution of sodium chloride (NaCl). The disinfectant is then circulated on the internal and external surfaces of re-usable heat-sensitive medical devices within a washer-disinfector AER with FDA-cleared

capability to maintain the solution temperature at 30°C used in hospitals, clinics and various other health care settings. It is a device intended for use by qualified healthcare personnel trained in its use.

The Sterilox device is similar in design, materials and intended use to other 510(k) cleared devices/instruments which are in commercial distribution.

### **1.8 Substantially Equivalent Commercially Available Devices:**

The Sterilox Liquid Chemical High Level Disinfectant System is substantially equivalent with respect to indications for use, device design, materials, and method of manufacture to the following commercially available predicate device:

Sterilox High Level Disinfectant System ~ (K013280)

Sterilox is also equivalent to other commercially available and marketed Unclassified and Class II devices indicated for use as liquid chemical sterilants/high level disinfectants.

### **1.9 Substantial Equivalence Comparison:**

The Sterilox Liquid Chemical High Level Disinfectant System is similar to commercially available devices with respect to intended use, material, design and operational principles as follows:

**1.9.1 General:**

	<b>Sterilox Liquid Chemical High Level Disinfectant System (System and HLD)</b>	<b>Predicate Device Sterilox Liquid Chemical High Level Disinfectant System (System and HLD) (K013280)</b>
<b>Labeling</b>	High Level Disinfectant	High Level Disinfectant
<b>Intended Use</b>	Disinfect reusable heat-sensitive medical devices which contact normally sterile areas of the body  Intended for use by qualified healthcare personnel trained in its use.	Disinfect reusable heat-sensitive medical devices which contact normally sterile areas of the body  Intended for use by qualified healthcare personnel trained in its use.
<b>Human Factors</b>	Dispensed ready to use by trained personnel	Dispensed ready to use By trained personnel
<b>Design, Construction, Components</b>	Aqueous solution Used in a stand alone Washer/Disinfector	Aqueous solution Used in a stand alone Washer/Disinfector
<b>Process Monitors</b>	Pre-programmed colorimeter for direct-reading of chlorine concentration	Pre-programmed colorimeter for direct-reading of chlorine concentration
<b>Reuse</b>	Single use	Single use
<b>Software Controls</b>	Yes	Yes
<b>High level disinfectant</b>	10 min at 30°C at 400-450 ppm AFC	10 min at 25°C at 650-675 ppm AFC

### 1.9.2 Operational Principles:

The basic operational principles of the Sterilox Liquid Chemical High Level Disinfectant System and the predicate device are similar in that they result in high level disinfection of reusable medical equipment that is heat sensitive by putting their disinfectant in contact with the devices for a specified period of time and temperature, in dynamic conditions. The operating principles are compared as follows:

	<b>Sterilox Liquid Chemical High Level Disinfectant System (System and Germicide)</b>	<b>Sterilox Liquid Chemical High Level Disinfectant System (System and HLD)</b>
<b>Form</b>	Inputs of water & germicide	Inputs of water & disinfectant
<b>Control</b>	Software controlled	Software controlled
<b>Contact</b>	Liquid contact	Liquid contact
<b>Purpose</b>	To achieve high level disinfection by destroying viable forms of microbial life, when used according to labeling	To achieve high level disinfection by destroying viable forms of microbial life, when used according to labeling
<b>Mode of Action</b>	Sterilox exerts its germicidal effect by attacking the surface and plasma membrane proteins, impairing transport of solutes and the salt balance of bacterial cells (Pieterse <i>et al</i> , Water SA (1996) <b>22</b> (1); 43-48)	Sterilox exerts its disinfection effect by attacking the surface and plasma membrane proteins, impairing transport of solutes and the salt balance of bacterial cells (Pieterse <i>et al</i> , Water SA (1996) <b>22</b> (1); 43-48)

The parameters that are measured and displayed are generally the same as those for the predicate device.

### 1.10 Indications and Contraindications:

Relative indications and contraindications for the Sterilox Liquid Chemical High Level Disinfectant System and commercially available devices for similar intended uses are the same.

### 1.11 Microbiological Efficacy:

The Sterilox germicide is a single use solution and all efficacy testing was conducted at or below the MRC of 400 ppm AFC.

Test Method	Test Organisms	Results
Sporicidal Activity of Disinfectants; AOAC Official Method 966.04 <sup>1</sup>	<i>Bacillus subtilis</i> <i>Clostridium sporogenes</i>	Meets liquid chemical High level disinfectant efficacy requirements
Confirmatory Sporicidal Activity of Disinfectants; AOAC Official Method 966.04 <sup>1</sup>	<i>Bacillus subtilis</i> <i>Clostridium sporogenes</i>	Meets liquid chemical High level disinfectant efficacy requirements
Fungicidal Activity of Disinfectants (AOAC 6.3.02:1995, Official Method 955.17)	<i>Trichophyton mentagrophytes</i>	Solution is fungicidal
Use-Dilution Method (AOAC 6.2.01:1995, Official Methods 955.14, 955.15, 964.02)	<i>Salmonella choleraesuis</i> <i>Staphylococcus aureus</i> <i>Pseudomonas aeruginosa</i>	Solution is bactericidal
EPA Virucidal Testing (DIS/TSS-7, Nov. 1981)	<i>Poliovirus II</i>	Solution is virucidal
Quantitative Tuberculocidal Test	<i>Mycobacterium bovis</i>	Solution is tuberculocidal
Simulated Use Test	<i>Mycobacterium terrae</i> <sup>2</sup>	Meets efficacy requirements
Clinical In-Use	Organisms remaining on flexible endoscopes after clinical use	No surviving microorganisms on any of the endoscopes tested.

<sup>1</sup>This testing was conducted in accordance with AOAC Official Method 966.04, except that polyester loops (instead of silk loops) were used as a carrier.

<sup>2</sup>Simulated use testing was conducted using actual used flexible endoscopes whose external surfaces and internal channels were contaminated with  $>10^6$  cfu *Mycobacterium terrae*. The inoculated scopes were processed in Sterilox and AER for 10 minutes at 30° C.

**1.12 Residue Data:**

Residue testing was performed to quantify any residuals remaining after disinfection with Sterilox above MRC and rinsing according to the label claims. The endoscope was then extracted and the eluates analyzed for residual Sterilox components. The results showed that Sterilox germicide well above its maximum use concentration is effectively removed from a complex device such as a flexible endoscope by the rinse cycle after disinfection and therefore poses no additional risk to the patient or user of the device.

**1.13 Toxicological Evaluation of Sterilox:**

Testing was performed to determine the potential toxicological effects of exposure to Sterilox liquid chemical High Level Disinfectant. The results are summarized as follows:

Skin Irritation (Rabbits)	Non-irritating
Skin Sensitization (Guinea Pig)	Non-sensitizing
Acute Dermal Toxicity (Rabbits)	Dermal LD <sub>50</sub> > 2 g/kg body weight
Acute Oral Toxicity (Rats)	Dermal LD <sub>50</sub> > 5 g/kg body weight
Primary Eye Irritation (Rabbits)	Non-irritating
Bacterial Mutation Assay	Non-mutagenic
Cytotoxicity	Non-cytotoxic

In section III.I.3 'Evaluation of toxicity' of the guidance for industry and FDA reviewers indicates the tests that should be considered when evaluation the biocompatibility of the germicidal product or the individual ingredients.

**1.14 Patient toxicity:**

Skin irritation and skin sensitization maximization test have been conducted on the product, Sterilox germicide. The test reports indicate that the studies were conducted properly. There were no indications of irritation or sensitization. Although positive results of studies on cytotoxicity and on haemocompatibility might be predicted from knowledge of the effects of hypotonic aqueous solutions generally, these results would also be expected of any suitably disinfected water used to rinse equipment.

As the toxicity of the product is essentially similar to that of chlorine based disinfectants, it is unlikely that any useful information will be obtained from further studies and it is therefore undesirable on the grounds of animal welfare to conduct these studies.

**1.15 User toxicity:**

An acute oral toxicity test (by the OECD 'fixed dose' procedure), a primary eye

irritancy study and a bacterial mutagenicity study in *Salmonella typhimurium* (the 'Ames' test) have been conducted on the product, Sterilox germicide. The test reports indicate that the studies were conducted properly. The results of these tests indicated that Sterilox germicide is non-mutagenic and non-irritating to the eye.

As, for toxicological purposes, the product is essentially equivalent to chlorine disinfectant, the conclusion reached by the International Program on Chemical Safety in Environmental Health Criteria 216 (2000) concerning the toxic effects of these disinfectants in drinking water that:

"Evidence from animal and human studies suggests that exposure to chlorine, chlorite solutions, chloramine and chlorine dioxide themselves probably do not contribute to the development of cancer or any toxic effects".

This also applies to the Sterilox germicide solution, thus undertaking additional testing is scientifically unnecessary and, on animal welfare grounds the studies should be omitted.

#### **1.16 Toxicological Conclusion:**

For all practical purposes the health risks to patient and to operator arising from exposure to Sterilox germicide and diluted Sterilox germicide are minimal. The principal potential effect of the chemicals present in Sterilox would be irritation, but Sterilox does not exhibit this effect in tests. Sterilox is unlikely to pose a significant risk to either patient or user.

#### **1.17 Materials Compatibility:**

The material compatibility of the Sterilox germicide was evaluated by subjecting a variety of metallic, plastic, adhesive and rubber endoscope components to continuous immersion in Sterilox. The samples were inspected for, visible change, visible evidence of damage or any other change in appearance. Sterilox germicide does not produce any corrosion or other visible damage in the majority of endoscope components. Color changes and the "tack" of the coating of the outer endoscope sheaths were noted on some endoscopes. Corrosion was noted on anodized aluminum.

#### **1.18 Assessment of non-clinical performance data for equivalence:**

The Sterilox High Level Disinfectant System complies with:

The Essential Requirements of Annex I of the Medical Device Directive 93/42/EEC and is manufactured under a Quality System approved by LRQA (Notified Body No. 0088) complying with Annex VII & V of the Directive.

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The Sterilox Liquid Chemical High Level Disinfectant System intends to comply with the FDA guidance document "Content and Format of Pre-market Notification [510(k)] Submissions for Liquid Chemical High level disinfectants/High Level Disinfectants," dated January 3, 2000, where applicable.

#### **1.19 Conclusion:**

In accordance with the Federal Food, Drug and Cosmetic Act and 21 CFR Part 807, and based on the information provided in this pre-market notification, PuriCore concludes that the device, the Sterilox Liquid Chemical High Level Disinfectant System, is safe, effective and substantially equivalent to the predicate device as described herein.





Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Howard K. Mann  
Director Regulatory Affairs & Official Correspondent  
PuriCore, Incorporated  
320 King of Prussia Road, Suite 200  
Radnor, Pennsylvania 19087

APR - 2 2007

Re: K063159  
Trade/Device Name: Sterilox™ High Level Disinfectant System  
Regulation Number: 880.6885  
Regulation Name: Liquid Chemical Sterilants High Level Disinfectants  
Regulatory Class: II  
Product Code: MED  
Dated: March 23, 2007  
Received: March 26, 2007

Dear Mr. Mann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

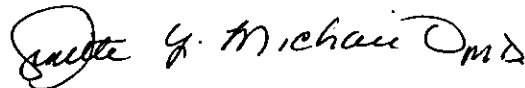
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Chiu Lin, Ph.D.", with a stylized flourish at the end.

Chiu Lin, Ph.D.  
Director  
Division of Anesthesiology, General Hospital,  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number: K063159

Device Name: **Sterilox™** High Level Disinfectant System

Indications for Use:

Sterilox™ is a high level disinfectant system intended for processing heat sensitive medical devices when used according to the User Manual with an immersion time of ten (10) minutes at 30°C. Sterilox is a single use product generated on site by the Maxigen II (E200) generator for use at its MRC of 400-450 ppm (AFC). The Sterilox high level disinfectant is intended for processing only in an automated endoscope reprocessor or washer disinfecter with FDA-cleared capability to maintain the solution temperature at 30°C.

The device is intended for use by qualified health care personnel trained in its use.

Prescription Use   X    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
Shukla H. Murphy, MD  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

510(k) Number:   K 063159